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United States Senate

SPECIAL COMMITTEE ON AGING WASHINGTON, DC 20510-6400 (202) 224-5364

August 1, 2025

ELIZABETH WARREN, MASSACHUSETTS MARK KELLY, ARIZONA RAPHAEL G. WARNOCK, GEORGIA ANDY KIM, NEW JERSEY ANGELA D. ALSOBROOKS, MARYLAND

The Honorable Mehmet Oz, M.D. Administrator U.S. Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

Dear Administrator Oz:

As the Senior Senator from Florida, I am committed to preserving the Medicare program for current and future generations. The Centers for Medicare and Medicaid Services (CMS) provides crucial health care to our seniors. I look forward to continuing to work with you to root out waste, fraud, and abuse within the Medicare program to ensure benefits are preserved as a safety net for those who need it. I commend CMS' release of a proposed rule in the CY 2026 Medicare Physician Fee Schedule to cut waste and enhance the quality of care for Medicare beneficiaries. I request information about CMS' efforts to detect and eliminate fraud within the Medicare program, particularly in the space of skin substitutes, which have seen unprecedented growth in costs to the Medicare program.

Medicare and Medicaid were responsible for approximately \$51 and \$50 billion each respectively of the \$236 billion of the fiscal year 2023 improper payments estimate. Despite this, CMS continues to provide payments for several skin substitute grafts and Cellular and Tissue-Based Products (CTPs) that no current Medicare Advantage or commercial plan covers. In a September 2024 report, GAO estimated that Part B spending on skin substitutes went from \$1.6 billion in 2022 to over \$10 billion in 2024. This unprecedented growth is even more stark when going back to 2019, where spending on skin substitutes was \$256 million. Skin substitutes are currently classified as biologicals by CMS, and payments can be as high as \$2,000 per square inch.

The HHS OIG released a report in 2023 identifying that 30 skin substitutes represent a disproportionate share of Medicare Part B spending. Additionally, this report found that CMS was unable to calculate Average Sales Price (ASP)-based payment amounts for these companies for the first quarter of 2023 despite them being statutorily required to report this data. In addition to this, companies have brought more than 100 new versions of product to market since 2023.

Identifying and ceasing improper payments will generate savings while preserving benefits for enrollees and is in line with the Trump administration's goal of eliminating waste, fraud, and abuse within the federal government.

CMS' proposed rule to shift payments to the incident to supplies model is projected to reduce spending on these products by approximately 90%. Steps like this that generate savings while maintaining quality of care are critical to protecting the Medicare program and preserving access for current and future beneficiaries. I am eager to support CMS in generating savings for the Medicare

The Honorable Mehmet Oz, M.D. August 1, 2025 Page Two

program to preserve benefits and prevent wasting of taxpayer dollars, and I ask that you answer the following questions:

- 1. What factors led CMS to propose the shift to the incident to supplies payment model for skin substitutes and move away from the Average Sales Price model?
- 2. Why does traditional Medicare Part B cover certain skin substitute products despite no Medicare Advantage or commercial plans covering these treatments?
- 3. Will CMS plan to nationally employ prior authorization for skin substitutes if the test is successful under the Wasteful and Inappropriate Service Reduction (WISer) model? What metrics would determine the success of the test model and what would be the timeline for its national implementation?
- 4. What actions did CMS take following the HHS OIG's report on skin substitutes? Was the Local Coverage Determination CMS issued a result of the HHS OIG's report on skin substitutes?
- 5. Do CMS' reporting requirements have enforcement mechanisms for skin substitute companies participating in the Average Sales Price +6 payment model? What mechanisms does CMS have in place for detecting anomalous billing practices on data that is reported?
- 6. How do the clinical value of a skin substitute and whether it is FDA-approved factor into the proposed shift to an incident to supplies payment model?
- 7. What is the dollar value of losses in savings to ACO-Reach and MSSP-ACO programs as a result of skin substitute payments billed to Medicare since 2019?

In order to preserve the Medicare program, it is essential that CMS continues to prioritize rooting out waste, fraud, and abuse and communicating this important work in a transparent manner to the hardworking American people who fund these programs and the vital benefits they provide to our citizens.

I look forward to our continued partnership and your prompt response as I work together to protect the Medicare program for current and future beneficiaries.

Sincerely,

Rick Scott Chairman

Senate Special Committee on Aging